

CONNOLLY BOVE LODGE & HUTZ LLP

The Nemours Building
1007 North Orange Street
P.O. Box 2207
Wilmington, DE 19899-2207
(302) 888-6316
Francis DiGiovanni (#3189)

MORGAN, LEWIS & BOCKIUS LLP

101 Park Avenue
New York, New York 10178
(212) 309-6000
Brian P. Murphy, Esq. (5162)

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

-----X	
GLAXO GROUP LIMITED	:
	:
	:
	:
Plaintiff,	:
	:
v.	:
	:
TEVA PHARMACEUTICALS USA, INC. and	:
TEVA PHARMACEUTICAL INDUSTRIES	:
LIMITED	:
Defendants.	:
	:
-----X	

REDACTED VERSION
D.I. # 99 and 100

Civil Action No. 04-171-KAJ

**DECLARATION OF OREN D. LANGER, ESQ., IN SUPPORT OF PLAINTIFF
GLAXO GROUP LIMITED'S OPENING CLAIM CONSTRUCTION BRIEF AND
SUMMARY JUDGMENT MOTIONS ON U.S. PATENT NO. 5,068,249**

I, Oren D. Langer, Esq., declare as follows:

1. I am an associate at the law firm of Morgan, Lewis & Bockius LLP, counsel to Plaintiff Glaxo Group Limited ("Glaxo").

2. I submit this declaration in support of Plaintiff's Opening Claim Construction Brief and Summary Judgment motions on U.S. Patent No. 5,068,249.

3. Attached as exhibit 1 is a true and complete copy of U.S. Patent No. 5,068,249 entitled, "Aqueous Ranitidine Compositions Stabilized with Ethanol" to Long.

4. Attached as exhibit 2 is a true and complete copy of highlighted portions of the trial testimony of Dr. John Wood taken in the *Glaxo v. Pharmadyne*, 32 F. Supp. 2d 265 (D. Md. 1998) matter on November 12, 1997.

5. Attached as exhibit 3 is a true and complete copy of highlighted portions of the trial testimony of Dr. David Long taken in the *Glaxo v. Pharmadyne*, 32 F. Supp. 2d 265 (D. Md. 1998) matter on November 12-13, 1997.

6. Attached as exhibit 4 is a true and complete copy of highlighted portions of Glaxo's Notice of Claimed Investigational Exemption for a New Drug ("IND") for Zantac® Syrup submitted to the FDA in or about November 1983.

7. Attached as exhibit 5 is a true and complete copy of highlighted portions of Glaxo's New Drug Application ("NDA") for Zantac® Syrup USP, 15 mg/ml submitted to the FDA on December 30, 1986.

8. Attached as exhibit 6 is a true and complete copy of a highlighted memo authored by Dr. David Long dated July 25, 1985, Plaintiff's Trial Exhibit 239 admitted into evidence in the *Pharmadyne* trial, and produced in this matter bearing production number G026878.

9. Attached as exhibit 7 is a true and complete copy of highlighted handwritten notes authored by Dr. David Long, Plaintiff's Trial Exhibit 242 admitted into evidence in the *Pharmadyne* trial, and produced in this matter bearing production

numbers G026880-82.

10. Attached as exhibit 8 is a true and complete copy of relevant highlighted portions of Lab Notebook P590, Plaintiff's Trial Exhibit 238 admitted into evidence in the *Pharmadyne* trial, and produced in this matter bearing production numbers G026714-877.

11. Attached as exhibit 9 is a true and complete copy of a highlighted memo authored by Dr. David Long dated August 28, 1985, Plaintiff's Trial Exhibit 241 admitted into evidence in the *Pharmadyne* trial, and produced in this matter bearing production number G026879.

12. Attached as exhibit 10 is a true and complete copy of highlighted portions of the certified file history of U.S. Patent No. 5,068,249.

13. Attached as exhibit 11 is a true and complete highlighted copy of a letter authored by Frank R. Sisto dated November 29, 1994 amending Glaxo's NDA for Zantac® Syrup, and produced in this matter bearing production number G023189.

14. Attached as exhibit 12 is a true and complete highlighted copy of a letter authored by John J. Gibbs, Ph.D. of the FDA acknowledging receipt of Glaxo's November 29, 1994 letter, approving Glaxo's supplemental NDA application, produced in this matter bearing production number G023126.

15. Attached as exhibit 13 is a true and complete copy of Teva Pharmaceuticals USA, Inc.'s response to Glaxo's Interrogatory No. 8 served on November 15, 2004.

16. Attached as exhibit 14 is a true and complete copy of Teva Pharmaceutical Industries, Ltd.'s response to Glaxo's Interrogatory No. 5 served on November 15, 2004.

17. Attached as exhibit 15 is a true and complete copy of highlighted portions of the trial testimony of Dr. Paul Wray taken in the *Glaxo v. Pharmadyne*, 32 F. Supp. 2d 265 (D. Md. 1998) matter on November 13 and December 18, 1997.

18. Attached as exhibit 16 is a true and complete copy of highlighted portions of the trial testimony of Dr. John M. Hempenstall taken in the *Glaxo v. Pharmadyne*, 32 F. Supp. 2d 265 (D. Md. 1998) matter on December 11, 1997.

19. Attached as exhibit 17 is a true and complete copy of a highlighted report authored by Mr. Nadeem Elahi dated May 15, 1990, Plaintiff's Trial Exhibit 247 admitted into evidence in the *Pharmadyne* trial, and produced in this matter bearing production number G026932-950.

20. Attached as exhibit 18 is a true and complete copy of highlighted portions of "Guidance for Industry – Guideline for Submitting Documentation for the Stability of Human Drugs and Biologics" published in February 1987 by the Center for Drugs and Biologics, Food and Drug Administration, Department of Health and Human Services.

21. Attached as exhibit 20 is a true and complete highlighted copy of 21 C.F.R. § 211.166 Stability testing (2006).

22. Attached as exhibit 21 is a true and complete highlighted copy of Plaintiff's First Set of Requests for the Production of Documents and Things to Teva Pharmaceuticals USA, Inc. Nos. 24 and 26-27 served in this matter on Sept. 15, 2004.

23. Attached as exhibit 22 is a true and complete highlighted copy of Plaintiff's First Set of Requests for the Production of Documents and Things to Teva Pharmaceutical Industries Limited Nos. 21 and 23-24 served in this matter on Sept. 15, 2004.

24. Attached as exhibit 23 is a true and complete highlighted copy of a letter from Teva's counsel transmitting documents to counsel for Glaxo dated December 6, 2005.

25. Attached as exhibit 24 is a true and complete copy of highlighted portions of the deposition transcript of Arthur H. Kibbe, Ph.D., taken in this matter on May 16, 2006.

26. Attached as exhibit 25 is a true and complete copy of highlighted portions of the deposition transcript of Annette Mattiuz, taken in this matter on November 3, 2005.

27. Attached as exhibit 26 is a true and complete copy of highlighted portions of the deposition transcript of Subrata Mazumder, taken in this matter on January 12, 2006.

28. Attached as exhibit 27 is a true and complete copy of Plaintiff's Deposition Exhibit 66, highlighted excerpts from Novopharm's Ranitidine Oral Solution Chemistry and Manufacturing Summary, bearing production numbers T07269-T07271.

29. Attached as exhibit 28 is a true and complete copy of relevant highlighted portions of Teva's Abbreviated New Drug Application ("ANDA") No. 76-937 for Ranitidine Oral Solution USP, 15 mg/mL.

30. Attached as exhibit 29 is a true and complete copy of Plaintiff's Deposition Exhibit 13, highlighted excerpts from Teva Laboratory Notebook No. 1853, bearing production numbers T06573 – T06575.

31. Attached as exhibit 30 is a true and complete highlighted copy of Plaintiff's Deposition Exhibit 102, an email from S. Lahtinen, Director, Regulatory

Affairs Project Management at Novopharm dated September 9, 2004, bearing production number T07268.

32. Attached as exhibit 31 is a true and complete copy of highlighted portions of the deposition transcript of John Fernandes, taken in this matter on March 3, 2006.

33. Attached as exhibit 32 is a true and complete copy of highlighted portions of the deposition transcript of Tamas Szederkenyi, taken in this matter on May 19, 2005.

34. Attached as exhibit 33 is a true and complete copy of highlighted portions of the deposition transcript of Leslie Kyle, taken in this matter on May 20, 2005.

35. Attached as exhibit 34 is a true and complete copy of Plaintiff's Deposition Exhibit 96, Notice of Deposition Pursuant to Rule 30(b)(6), Fed. R. Civ. P., served on counsel for Teva on September 19, 2005.

36. Attached as exhibit 35 is a true and complete highlighted copy of Plaintiff's Deposition Exhibit 92, an April 22, 2003 email sent by Wayne Cagno, bearing production numbers T010862-T010866 .

37. Attached as exhibit 36 is a true and complete copy of highlighted portions of the deposition transcript of Margaret Wrigley, taken in this matter on March 22, 2006.

38. Attached as exhibit 37 is a true and complete copy of highlighted portions of the deposition of Glaxo expert witness Bradley D. Anderson, Ph.D., taken in this matter June 8, 2006.

39. Attached as exhibit 38 is a true and complete copy of highlighted portions of Plaintiff's Deposition Exhibit 35 entitled, "Information Package: Ranitidine HCL Syrup" dated April 22, 2003, bearing production numbers T02051-T02055.

40. Attached as exhibit 39 is a true and complete highlighted copy of Teva

stability data bearing production numbers T01961-62 and T01966-67.

REDACTED

REDACTED

REDACTED

2

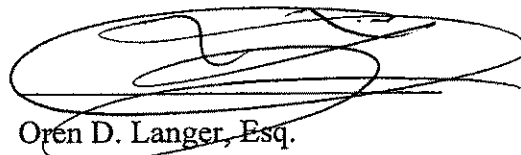
REDACTED

49. On November 4, 1998, the *Pharmadyne* court issued a Second Amended Judgment Order in Glaxo's favor. Attached hereto as Exhibit 48, is a true and complete copy of relevant highlighted portions of the court's Second Amended Judgment Order. The Order adds that Pharmadyne and its affiliates are permanently enjoined, restrained and prohibited from infringing claims 1 and 4-10 of the '249 patent, including making, using, selling, offering to sell and/or importing into the U.S., Pharmadyne's ANDA product.

50. On November 4, 1998, the *Pharmadyne* court's Findings of Fact and Conclusions of Law and its Second Amended Judgment Order were published as *Glaxo Wellcome, Inc. v. Pharmadyne Corp.*, 32 F. Supp. 2d 265 (D. Md. 1998).

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct to the best of my knowledge and belief.

Dated: June 29, 2006



Oren D. Langer, Esq.